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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/456,278

Examiner

Isis Ghali

Applicant(s)

MIRANDA ET AL.

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2, 4, 5, 8-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 3, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time and request for reconsideration, both filed 8/7/2001.

#### ***Response To Election/Restrictions***

1. Claims 2, 4, 5, and 8-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II and III and species a, b, and d, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.
2. Applicant's election with traverse of Group I and species c, claims 1, 3, 6, and 7 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the article of Group I can be made by method defined Group II and can be used in the method of use defined in Group III. The examiner has not explained why the three groups are considered to define independent subject matter and the examiner does not address the materially different process. Applicants also submitting that proper search of subject matter of each group cannot be done except that such a search is conducted for the subject matter of all three groups. This is not found persuasive because the article of Group I does not require to be made by the process of Group II that requires the hexane solvent and the step of evaporating the hexane. The patch can be made by suspending

or dispersing the active agent into the adhesive matrix without the need of solvent.

Furthermore, the particular structure of the patch of Group I and the particular method of making the patch of Group II are not required for carrying out the method of Group III.

The method of Group III is not requiring any particular transdermal structure or formulation and it can be practiced by applying cream or paste comprising the drug. The search system and the focus of the invention are completely different, requiring an undue burden on the patent examiner. While searches may seem to be overlapping, no reason to expect the searches to be un-extensive since the patent examiner searches the databases mostly literally. Rarely do applicants present claims to an inventions where the distinctness of the invention are readily clear such as a chemical compound and a gene sequence. It is the responsibility of the examiner to enforce 35 USC 101, which allows the applicant to obtain a patent for a single invention. In the opinion of the examiner the applicants present three distinct inventions.

The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

3. If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

***Specification***

4. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

6. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by US 6,264,977 ('977).

US '977 disclosed a transdermal therapeutic system mainly for the delivery of volatile active substance such as nicotine. The therapeutic system comprising an impermeable backing layer and detachable protective layer and in between there are two layers of active substance reservoir matrix. The two reservoir matrix layers are being the same or different consisting of pressure sensitive adhesive such as silicone rubber and acrylate adhesive. See the abstract; col. 3, line 30; col.4, lines 11-21, 57-67; col.5, lines 8-8-10, 52-53; col.6, line 5; col.7, line 12-14.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 3, 6, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '977 or US 5,316,759 ('759) each standing by itself or in combination.

The teachings of US '977 is discussed under 102 rejection above. However, the reference does not teach the drug as a combination of nicotine and mecamylamine and their doses.

US 759 is teaching the transdermal drug delivery of nicotine and mecamylamine combined in a single dose in the form of a patch. The patch comprising an impermeable backing; reservoir with silicone polymer matrix and the drugs; and releasable liner. The

patch provides a steady rate of delivery of 1-4 mg per hour of nicotine and 0.5-1 mg per hour of mecamlamine. See the abstract; col.3, lines 26-30; col.4, col.5, lines 6-9; col.6, lines 50-64; col.8, lines 6-8, 29-32, 43-50, 65-67; col.9, lines 19-41.

US '759 does not teach the multiple adhesive layers, which is taught by US '977.

It is within the skill in the art to construct a patch with multiple reservoir matrix layers of different adhesive composition. It is also well known in the art to treat addiction or drug dependency by administering the drug and its antagonist. The blend of acrylic adhesive is well known in the art and taught by US 5,656,286 as well as the siliconized release liner, which is disclosed by US 5,721,257.

The particular structure of the claimed patch comprising a layer of silicone adhesive and a layer of acrylic adhesive is not critical in administering both nicotine and mecamlamine in combination, absent evidence of the contrary.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver a transdermal patch comprising two different adhesive layers for delivering nicotine and mecamlamine with reasonable expectation of success of the obtained patch in treating nicotine dependency.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,141,750 and US 6,090,404 are disclosing transdermal delivery devices comprising multiple reservoir layers.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali  
Examiner  
Art Unit 1615

THURMAN K. PAGE  
SUPERVISOR  
EXAMINER  
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